Applicant : Russell A. Houser
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Filed : August 4, 2000
Page : 9

Client's Reference No.: 23,393-37

2-8, 11-14, 16-18, 20, 23-25
27-29

REMARKS

In view of the above amendment and the following remarks, reconsideration and allowance of this application are requested. Claims 1-29 are pending with claims 9, 15, 21, and 22 being withdrawn from consideration. Claims 1, 10, 19, and 26 are independent.

Claim 1 is rejected as being anticipated by Okada (U.S. Patent No. 4,638,802) and Okada et al. (U.S. Patent No. 3,910,279). Claim 1 is directed to a device for performing percutaneous transmyocardial revascularization and includes an elongate catheter, a cutting element, and a control component. The elongate catheter has a proximal end and a distal end, a catheter wall defining a compartment within the catheter, and at least one window through the catheter wall open to the compartment. The cutting element is compressible into a reduced diameter when positioned within the compartment and tends to radially expand beyond the catheter wall when positioned near the at least one window. The control component is coupled to the cutting element and operable to selectively position and move the cutting element to a location near the window to allow the radial expansion through the window.

Okada et al. is directed to an insulating tube 1 that includes a distal end that has an opening 2 through the side of the tube. A distal end 5 of a wire 3 is fixed at the distal end of the insulating tube and can be projected out of the opening 2 to form a loop 6 to cut tissue. See Figs. 4-6. Okada et al. states that the wire 3 can be pushed into the tube such that the loop 6 is formed. See col. 3, lines 59-67. The wire 3 appears to correspond most closely to the cutting element of claim 1. However, the wire 3 of Okada et al. is not compressible into a reduced diameter nor does it tend to radially expand beyond the catheter wall, as recited in claim 1. Instead, as stated by Okada, the wire must be pushed to form the loop:

> "When, as later described, the wire 3 is pushed toward the forward end portion 1a along the axial line of the tube 1 as indicated by an arrow of FIG. 1, it is made to round out in the form of a large loop transversely to the axial line of the tube 1 as denoted by two dots-and-dash lines of Fig. 1. .... In other words, upon pushing-into operation of the wire 3 the working section 6 is outwardly looped in a manner going away from the outer circumference of the tube 1 along the axial line thereof[.]"
>
> See col. 3, lines 53-66.

"[T]he condition in which the wires 3 and 30 are forced into the tube 1 to permit both working sections 6 and 60 to be largely looped exteriorly of the tube 1 is shown."

See col. 7, lines 10-15.

Okada et al. also shows that the operator causes the wire to radially expand beyond the catheter wall (i.e., the wire does not have the tendency to expand beyond the catheter wall), rather than the cutting element tending to radially expand beyond the catheter wall, as recited in claim 1:

"{T]he pushing-into or drawing-out operation by an operator of the wire 3 is carried out along the axial line of the tube 1[.]"

See col. 3, line 67 through col. 4, line 2.

"Namely, the operator moves the knob member 11 in a direction in which it approaches the grip member 9, with the grip member 9 held by the fingers of one hand and the knob member 11 held by the fingers of another. Then, the wire 3 is forced into the tube 1 to permit the working section 6 to be outwardly looped as indicated by two dots-and-dash lines of Fig. 1. On the other hand, if the operator moves the knob member 11 in a direction in which it goes away from the grip member 9, the wire 3 will be drawn out from the tube 1, so that the working section 6 is returned to the shrunk state[.]"

See col. 5, lines 51-63 (emphasis added).

"When the body section 400 is pushed in an arrow-indicated direction by the manual operation of the operator, the both working sections 6 and 60 are projectively looped exteriorly of the tube 1. On the other hand, when the body section 400 is pulled in the opposite direction, the two looped working sections 6 and 60 are shrunk at the same time."

See col. 7, lines 55-62.

For at least these reasons, claim 1 is allowable over Okada et al.

Okada discloses a wire electrode that extends from the tip of a catheter (Fig. 6) or a window in the wall of the catheter (Fig. 8). The wire rests adjacent to the window but when the operator advances the wire (see col. 4, lines 50-56) by pushing the fixture 15, because the distal end of the wire is fixed to an anchorage 39 (see Fig. 8 and col. 6, lines 9-15), advancing the fixture 15 pushes the wire out of the window. Okada further discloses how the loop is formed: "[a]s the wire electrode 20 moves forward through the opening 18, a semi-circular loop 24 is

formed at the distal end thereof (see Fig. 6)." See col. 5, lines 7-9 and Fig. 6. Only Fig. 8 of Okada discloses a window through the catheter wall open to the compartment. Assuming that the wire electrodes of Okada correspond to the cutting element of claim 1, Okada does not describe or suggest a cutting element that is compressible into a reduced diameter when positioned within the compartment and tends to radially expand beyond the catheter wall when positioned near the at least one window, as recited in claim 1. Instead, Okada describes the wire electrode as being advanced and then projecting laterally to form a loop rather than tending to radially expand beyond the catheter wall when positioned near the window. See col. 6, lines 32-40. Because the wire electrode of Okada is always positioned near the window, in fact beside the window, and does not radially extend beyond the catheter wall except when advanced by the operator, Okada's wire electrode cannot be said to tend to radially expand beyond the catheter wall when positioned near the at least one window, as recited in claim 1. Moreover, Okada's wire electrode cannot be said to be compressed into a reduced diameter when positioned within the compartment because when positioned within the compartment, there is no compressive force described or suggested for causing this positioning. For at least these reasons, claim 1 is allowable over Okada.

Claims 2-8, 10-14, 16-20, and 23-29 are rejected as being obvious over Okada or Okada et al. in view of Parins (U.S. Patent No. 4,976,711).

Claims 2-8 depend from claim 1 and are allowable over Okada and Okada et al. for the same reasons that claim 1 is allowable over Okada and Okada et al. Claims 2-8 are also allowable over Okada or Okada et al. in view of Parins because Parins does not cure the deficiency of either Okada or Okada et al. to describe or suggest a cutting element that is compressible into a reduced diameter when positioned within the compartment and tends to radially expand beyond the catheter wall when positioned near the at least one window, as recited in claim 1.

Parins is directed to an ablation catheter with deployable electrodes that are adjacent a window. See Figs. 2, 4 and 5 and col. 4, lines 29-38. Parins describes an important aspect of the invention as being the ability to route the catheter through the vascular system with the catheter having a low cross-sectional profile and then upon reaching the site for ablation increasing its cross-sectional profile to contact the electrodes against tissue to be ablated. See col. 3, lines 39-

48. Parins describes one means of contacting the electrodes against the tissue as inflating a balloon 40. However, assuming that the electrodes correspond to the cutting element of claims 2-8, Parins does not describe or suggest a cutting element that is compressible into a reduced diameter when positioned within the compartment and tends to radially expand beyond the catheter wall when positioned near the at least one window, as recited in claims 2-8. In fact, Parins' electrodes of Figs. 1-7 are always positioned within the window and in that position, and all other positions, are neither expanded nor compressed, much less tending to radially expand beyond the catheter wall, as recited in claims 2-8. For at least this reason, claims 2-8 are allowable over Parins taken separately or in combination with either Okada or Okada et al.

Claim 10 is directed to an elongate catheter for cutting incisions into heart tissue. The catheter includes at least one window, at least one support strand, a cutting element, and a first control component. The at least one window through the catheter wall is adapted to be positioned against a first tissue surface such that the at least one window faces the first tissue surface. The at least one support strand is adapted to be manipulated into contact with a second tissue surface separate from the first tissue surface to force the at least one window into contact with the first tissue surface. The cutting element has a tendency to expand beyond the catheter wall when positioned near the at least one window to contact the first tissue surface when positioned near the at least one window such that the cutting element cuts tissue adjacent the at least one window to a predetermined depth determined by the shape of the cutting element. The first control component is coupled to the cutting element and operable to selectively position and move the cutting element along the at least one window.

However, neither Okada et al. nor Okada in view of Parins, taken separately or in combination, describes or suggest an elongate catheter having a cutting element that has a tendency to expand beyond the catheter wall when positioned near the at least one window to contact the first tissue surface when positioned near the at least one window such that the cutting element cuts tissue adjacent the at least one window to a predetermined depth determined by the shape of the cutting element, as recited in claim 10. Instead, as described above, Okada et al. discloses a wire that must be forced or pushed to form the loop, i.e., the wire does not have a tendency to expand beyond the catheter wall. For example, Okada et al. discloses the wire

electrode being positioned adjacent to a window in the catheter wall. Nonetheless, the wire electrode does not extend from the window unless the wire is advanced into the catheter to force the wire electrode through the opening. This is not the same as having a tendency to expand beyond the catheter wall when positioned near the at least one window, as recited in claim 10.

Similarly, Okada discloses the wire electrode as being positioned adjacent to a window in the catheter wall. See Fig. 8. Nonetheless, the wire electrode does not extend from the window unless the wire is advanced into the catheter to force the wire electrode through the opening. This is not the same as having a tendency to expand beyond the catheter wall when positioned near the at least one window, as recited in claim 10.

Parins' electrodes (see Figs. 1-7) are always in the same position relative to the window (i.e., fixed position relative to the window) and do not have a tendency to expand beyond the catheter wall when positioned near the window, as recited in claim 10. As shown, for example, in Figs. 4 and 5, the electrodes engage the vessel through the opening in the wall only by forcing the catheter against the vessel rather than relying on a tendency of the electrodes to expand when positioned near the window. Again, this is not the same as having a tendency to expand beyond the catheter wall when positioned near the at least one window, as recited in claim 10.

Thus, neither Okada et al., Okada, or Parins, taken separately or in combination, describe or suggest a cutting element that has a tendency to expand beyond the catheter wall.

For at least this reason, independent claim 10 and dependent claims 11-14 and 16-18 are allowable over Okada et al., Okada, and Parins, taken separately or in combination.

Claim 19, like claim 10, recites a catheter in which the cutting element has a tendency to expand beyond the catheter wall. Accordingly, claim 19 and dependent claims 20 and 23-25 are allowable over Okada et al., Okada, and Parins, taken separately or in combination.

Claim 26, like claim 10, recites a cutting element that has a tendency to expand beyond the catheter. Accordingly, claim 26 and dependent claims 27-29 are allowable over Okada et al., Okada, and Parins, taken separately or in combination.

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Serial No. : 09/632,519
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Page : 14

Client's Reference No.: 23,393-37

Applicant respectfully submits that all claims are condition for allowance. A petition for a two month extension of time and a payment of the extension of time fee of $205 are included.

Respectfully submitted,

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